NDA 16-418/S-071
NDA 16-419/S-022
NDA 18-553/S-027

AUG 22 1999

Wyeth-Ayerst Laboratories
Attention: Ms. Roberta R. Acchione
170 North Radnor-Chester Road
St. Davis, PA 19087-522 1

Dear Ms. Acchione:

Please refer to your supplemental new drug applications dated August 27, 1998 submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Inderal (propranolol hydrochloride), 10, 20,40, 60 and 80 mg Tablets (NDA 16-418), Inderal (propranolol hydrochloride) 1 mg Injection (NDA 16-419) and Inderal LA (propranolol hydrochloride) 60, 80, 120 and 160 mg Capsules (NDA 18-553).

We acknowledge receipt of your submissions dated July 23, 1999.

These supplemental new drug applications provide for final printed labeling revised as follows:

1. Under the header, the sentence, “Caution: Federal law prohibits dispensing without a prescription.” has been replaced with, “Rx only.”

2. Under the WARNINGS/Diabetes and Hypoglycemia subsection, the phrase, “... in patients on propranolol” has been added to the last sentence of the first paragraph.

3. Under the WARNINGS/Diabetes and Hypoglycemia subsection, the word, “subjects” has been replaced with, “patients” in the last sentence of the last paragraph.

4. The following subsection has been added to the PRECAUTIONS section:

   Geriatric Use:
   Clinical studies of propranolol did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of the decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling included in your on July 23, 1999 submission. Accordingly, the supplemental applications are approved effective on the date of this letter.

If you have any questions, please contact:

Zelda McDonald
Regulatory Project Manager
(301) 594-5333

Sincerely yours

Raymond I. Lipicky
Director
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Office of Drug Evaluation I
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